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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,759	SHAPIRO, PHYLLIS	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-24* is/are rejected.

7)☒ Claim(s) *1,9 and 14* is/are objected to.

8)☒ Claim(s) *1-3 and 5-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments and remarks in Paper No. 9, filed 5/15/03, are acknowledged. Amended claims 1-2, 5, 7, 9-12, 14-19, 21-22; canceled claim 4; and new claim 24 are acknowledged.

Applicant's arguments, filed 5/15/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3 and 5-24 are herein under examination.

Claim Objections

Claims 1, 9, and 14 are objected to because of the following informalities:

Claim 1 (line 7) and claim 9 (line 13) state the number "3" in "(cells/mm3)" which should be in superscript form to properly denote the described concentration. (The original claims had this superscript issue correctly denoted).

Claim 14 (line 2) is objected to because of the comma after the number "10" appears to be improper.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-23 are rejected due to the claim steps lacking correspondence to the preamble of these claims. In claim 16, the claim steps only contain correction factors multiplied by plasma or serum hemoglobin values when in actuality, the preamble states a method for correcting values in blood, plasma, or serum. Thus, it is unclear whether the preamble or the correcting step in this claim controls the metes and bounds of the claimed invention. Appropriate clarification of the metes and bounds of the claim via clearer claim wording is requested. Claim 23 is rejected due to a similar issue with the preamble in claim 15 from which it depends. Claims 17-22 are also rejected due to their direct or indirect dependency from claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-3, 5-15, and 17-22 is maintained and newly applied to new claim 24 under 35 U.S.C. 103(a) as being unpatentable over Chupp et al. (P/N 5,631,165) in view of Chang et al. (P/N 5,200,323) and Malin et al. (Patent Application Publication No. 2002/0012904).

Applicant amended the claims to include claim language such as "for interference in" claim 1 (lines 1 and 16) and similar wording in claims 9 (line 7), 15 (line 12), and 16 (line 14). Applicant states that Chupp et al. and Chang et al. fail to teach or suggest the correction of interference in blood, plasma, or serum samples comprising an exogenous heme-colored blood substitute (Response, page 23, lines 17-21). This is found unpersuasive as Chupp et al. describe a device to distinguish and differentiate cells in whole blood samples (col. 7, third paragraph) suggesting that something is interfering with the cells being analyzed. The mere mention of "correction" (see "correction factors", Chupp et al.; col. 63, lines 23-35; col. 5, lines 49-53; and col. 6, paragraph 6) suggests that some type of interference among cells has taken place which is why correction is subsequently taking place. The 35 USC § 103(a) rejection in the last Office Action, mailed 1/15/03 (and repeated, *infra*), provided motivation to include recombinant human hemoglobin which is an exogenous heme-colored blood substitute, as stated by Chang et al. (col. 3, lines 61-63) in the Chupp et al. invention. One of recombinant human hemoglobin's inherent features is the heme-color (Chupp et al. col. 1, lines 32-33) which was an added limitation in claims 2, 9, 10, 12, 15, 16, 17, and 19. The added limitation of "determined by cell-by-cell measurements" in claim 1 (lines 6-7 and 11-12), as stated Malin et al. in claim 13 (further explained, *infra*), is a step well known in the art of cytometry.

Chupp et al. teach a system where information about the blood sample is entered into the controller of an automated system which activates the analyzers to perform analyses under the direction of the controller (col. 10, lines 54-67). Chupp et al. describe the system as including an analyzer module, a data station module, and a pneumatic unit (col. 11, lines 27-29). The data station module has "sufficient software algorithms to manipulate measured data, calculate parameters and display results in a variety of formats" (col. 11, lines 62-67). Chupp et al. further discuss the analyzer module in which sample tubes of blood are automatically transported with bar code labels that can be read with a bar code reader so that sample information can be inputted into the system controller (col. 25, lines 22-35). Chupp et al. teach correcting MCH and MCHC in blood by performing the mathematical computations described in b(1) – (2) of claim 9 where the constants to correct dimension units for formula 1 is 10 and for formula 2 is 100 (col. 53, lines 66-67 and col. 54, lines 1-26). Chupp et al. teach the use of setting hemoglobin flags if any results are abnormal or suspect (col. 61, lines 50-51) which suggests the blood sample tested may be normal or abnormal as stated in claim 3. Chupp et al. also describe anemic patients with increased reticulocyte counts as indicating rapid erythroid turnover suggesting acute blood loss or hemolysis (col. 1, lines 62-65) as stated in claims 5 and 6. However, Chupp et al. do not teach the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin or the formulas being determined by cell-by-cell measurements.

Chang et al. describe the use of modified hemoglobin blood substitutes as alternatives to human donor blood, such as recombinant human hemoglobin (col. 3, lines 61-63).

Malin et al. describe using automated methods and hematology systems for differentiating and accurately measuring the contribution of an added or exogenous hemoglobin

product or blood substitute separately and distinctly from the contribution of cellular hemoglobin which derives from a patient's red blood cells (page 2, paragraph 0012). Malin et al. describe determining, measuring, and/or monitoring hemoglobin-based red cell substitutes, or oxygen-carrying substitutes, such as recombinant hemoglobin products, in whole blood, plasma, or serum samples (pages 2-3, paragraph 0020). Malin et al. describe using cell-by-cell measurements in claim 13.

Chupp et al. describe the presence of classes and subclasses of red blood cells (col. 3, lines 53-54) and how the two methods used can distinguish cells and subdivide the cell types into finer classifications (col. 3, lines 7-14). Chupp et al. also discuss the need for increasing the precision and accuracy of previous manual methods of hematology analysis by using automated systems (col. 7, lines 11-16). Chang et al. point out it would be highly desirable to screen human blood and plasma to determine the safety of modified hemoglobin blood substitutes for humans (col. 4, lines 11-30). A skilled artisan in the art would have been motivated to enhance the automated hematology analyzer and method for correcting MCH and MCHC values in blood, as stated by Chupp et al., by including all types of blood samples in use at the time of the invention such as those containing modified hemoglobin blood substitutes, as stated by Chang et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use samples including recombinant human hemoglobin and other modified hemoglobin blood substitutes (as stated by Chang et al. and Malin et al.) in automated methods and systems of obtaining accurate MCH and MCHC values (as stated by Chupp et al. and Malin et al.), including the cell-by-cell measurements which are well known in the art of cytometry as exemplified by Malin et al., because this information would enhance understanding

of safety and potential problems of the various types of blood and blood substitutes in humans at the time of the invention, as stated by Chang et al. (col. 4, lines 11-30). Thus, Chupp et al., in view of Chang et al. and Malin et al., motivate the limitations in claims 1-3, 5-15, 17-22, and 24 of the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 6, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER